UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS INTERNATIONAL PHARMACEUTICAL AG, *Plaintiff*, v. INCYTE CORPORATION, *Defendant*.	Case No. 20-cv-00400-GHW Hon. Gregory H. Woods

MEMORANDUM OF LAW IN SUPPORT OF INCYTE CORPORATION'S MOTION TO DISMISS

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Defendant Incyte Corporation ("Incyte") moves to dismiss the Complaint of Plaintiff Novartis International Pharmaceutical AG ("Novartis") under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.

INTRODUCTION

Incyte is a pharmaceutical company dedicated to research and development of new drugs to treat patients with serious unmet medical needs. Incyte discovered and developed a drug compound known as ruxolitinib, a kinase inhibitor that Incyte sells in the U.S. under the trade name JAKAFI® for treatment of certain rare blood cancers and related conditions. Incyte sought a licensing deal with Novartis to facilitate commercialization of the drug outside the United States. In November 2009, the companies entered into a Collaboration and License Agreement (the "Agreement") creating a cross-licensing arrangement by which Incyte sells JAKAFI® in the U.S., and Novartis sells ruxolitinib abroad.[1]

Despite the shared success of this partnership, Novartis improperly seeks to rewrite the Agreement to materially increase the tenor and quantum of Incyte's royalty obligations to Novartis on U.S. sales of JAKAFI®. Novartis does so by ignoring the plain language of two key definitions—the definition of "Licensed Patent Rights" in Section 1.67 and the definition of "Regulatory Exclusivity" in Section 1.101. These definitions are used in Section 8.3(c), which, despite their plain language, Novartis seeks to apply in such a way as to increase by seven or more

[1] The Agreement is appended as Exhibit 1 to the Declaration of Daniel P. Mach. It is referenced extensively in the Complaint, and therefore may be considered on this motion. *See Children's Apparel Network Ltd. v. Twin City Fire Ins. Co.*, 2019 WL 3162199, at *2 (S.D.N.Y. June 26, 2019) ("A court 'may [also] consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference … and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit.'") (quoting *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)); *see also Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991).

years the term during which Incyte is obligated to pay royalties on Incyte's U.S. sales and also to prevent Incyte from availing itself of a contractually-negotiated "step-down" in the percentage royalties on those sales. Novartis claims that Incyte has breached the Agreement by invoking the royalty step-down, but in reality that claim is simply a strategy by Novartis to extract profits that Novartis never bargained for, over and above the substantial commercial gains Novartis already made and continues to make from its license to Incyte's invention and intellectual property. Because the unambiguous text of the Agreement precludes Novartis's claims of breach, the Complaint should be dismissed.

The business deal memorialized in the Agreement provides that Incyte will commercialize ruxolitinib in the Incyte Territory (the U.S. and its territories) and Novartis will do so in the Novartis Territory (the rest of the world). The Agreement sets a schedule of royalties that each company pays to the other. Each company pays royalties quarterly, on a "product-by-product" basis, on its net sales within each country in its Territory for the duration of a "Royalty Term." That term lasts from the First Commercial Sale in the country through "the longer of: (i) the last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country; (ii) ten (10) years following the date of First Commercial Sale in such country; and (iii) the expiration of Regulatory Exclusivity for such Licensed Product in such country." Agreement § 8.3(c). But if, during the ten-year minimum term, there is neither any Valid Claim of Licensed Patent Rights Covering sales of the product (Subpart (i)) in a country nor Regulatory Exclusivity for the product (Subpart (iii)) in that country, the royalty rate for that country is reduced to 50% of the otherwise applicable rate. *Id.*

Incyte obtained U.S. FDA approval to sell JAKAFI® to treat its first medical indication, the bone marrow disorder myelofibrosis ("MF"), in November 2011 and made its First

Commercial Sales in or about that month. After Incyte made its First Commercial Sales in 2011, Incyte began paying Novartis the full percentage royalty because JAKAFI® was subject to "Regulatory Exclusivity" in the U.S. as a result of the FDA's having granted an "Orphan Drug Designation" relating to the only then-approved indicated use of JAKAFI®—*i.e.*, for the treatment of MF. This FDA designation is reserved for drugs that treat diseases affecting fewer than 200,000 people in the U.S. and imparts in certain circumstances a regulatory right, referred to as Orphan Drug Exclusivity ("ODE"), to exclude competition from selling a drug for that indication for seven years. Incyte continued to pay the full royalty through the end of 2018 because, until November 2018, all approved indicated uses for JAKAFI® were covered by Orphan Drug Designations. But ODE for the MF indication expired in November 2018, and so Incyte utilized the 50% step-down in royalty rates provided for in the Agreement beginning in the first quarter of 2019.

Novartis challenges Incyte's application of the 50% royalty step-down. Its Complaint sets forth two positions, neither of which has any merit or grounding in the contract.

First, Novartis asserts that Incyte's U.S. sales are "Covered by a Valid Claim of Licensed Patent Rights," such that Section 8.3(c)(i) precludes Incyte from applying the step-down. It is undisputed, however, that while the Agreement contemplated that Novartis might obtain licensable U.S. patent rights, Novartis never did so and therefore does not license any U.S. patents to Incyte. Thus, Novartis contends that Section 8.3(c)(i) continues as long as ***any*** patents exist in a country, regardless of which party owns those patents and whether or not the royalty-paying party (here Incyte) made its relevant sales pursuant to any license granted by the royalty-receiving party (here Novartis). Novartis's argument that Incyte's non-expired U.S. patents require Incyte to pay a full royalty reads out of the Agreement the definition of "Licensed Patent Rights" in Section 1.67—a definition that was created solely for purposes of Section 8.3(c) and that clearly distinguishes

between the "Incyte Patent Rights" licensed to Novartis and the "Novartis Patent Rights" licensed to Incyte. This Court should apply the plain language and reject Novartis's reading.

Second, Novartis claims that JAKAFI® maintains "Regulatory Exclusivity" in the U.S., so that Section 8.3(c)(iii) requires Incyte to continue to pay full royalties. Novartis's position is that, despite the expiration of ODE for MF,[2] Regulatory Exclusivity still exists because the two secondary indications—polycythemia vera ("PV") and acute graft-versus-host-disease ("GVHD")—have ODE. Novartis's argument equates regulatory exclusivity of any kind with that explicitly defined in the Agreement. "Regulatory Exclusivity" is defined in Section 1.101 to exist only as long as Incyte has a regulatory ***right to exclude any*** third-party activities to bring the drug to market, which it no longer has with respect to JAKAFI®. While the ODEs for PV and GVHD bar generic drug manufacturers from labeling a generic version of JAKAFI® for these two indications, they pose no barrier to FDA approval of a generic drug labeled for MF only—which can be sold and labeled to treat MF and prescribed for the other indications. Thus, the current FDA regulatory status does not afford Incyte the "ability to ***exclude***" generic competitors from "Commercializing" a generic alternative in the U.S., and does not provide "Regulatory Exclusivity" as defined in the Agreement.

Accordingly, the Royalty Term governing Incyte's royalty obligations on its U.S. sales continues solely under Subpart (ii) of Section 8.3(c), and the royalty rate is accordingly reduced to 50% of the rate otherwise payable.

The crux of the parties' dispute is whether the conditions of Section 8.3(c)(i) and 8.3(c)(iii) have been met, reducing the royalty rate and limiting the royalty term to its 10-year default. Both

[2] JAKAFI® also was previously subject to a New Chemical Exclusivity, a separate regulatory right to exclude that expired after five years, before ODE expired for the MF indication.

parties agree that the Agreement is unambiguous, and the key issue in dispute is whose interpretation of Sections 8.3(c)(i) and (iii) and the related definitional terms is correct. The dispute thus may be resolved as a matter of law and within the four corners of the Agreement. For the reasons set forth herein, Incyte's interpretation is the correct one.

It is noteworthy, however, that the error of Novartis's interpretations of these royalty provisions goes beyond their clear conflict with the text of the Agreement. They would also create a commercial absurdity, by which the term over which Incyte pays Novartis royalties would extend nearly two decades, from 2011 until at least 2028, far longer than the 10-year default term length contemplated by Section 8.3(c)(ii). Worse, that term would be automatically extended any time Incyte obtains a new patent of its own or a new regulatory approval—a result that would frustrate the purpose of the Agreement by penalizing Incyte, the licensor, for obtaining new patents and approvals that have the potential to increase the medical and commercial value of ruxolitinib and thereby to enhance Novartis's ability to commercialize the drug in the Novartis Territory.

BACKGROUND

For purposes of this motion, Incyte takes as true all factual allegations in the Complaint, incorporating the Agreement and judicially noticeable facts as permitted on a motion to dismiss.

A. Incyte's Development Of Ruxolitinib

In the mid-2000s, Incyte scientists invented and developed ruxolitinib for treatment of certain chronic rare blood cancers and other serious diseases. Compl. ¶ 25. Incyte sells ruxolitinib in the U.S. under the name JAKAFI®. *Id.* ¶ 3. Ruxolitinib has been highly successful in treating several medical conditions, including intermediate or high-risk MF, PV, and GVHD. *Id.*

In 2009, before ruxolitinib was approved to treat any of these indications, Incyte was a small company with a valuable asset, a compound that it had discovered and put through successful clinical trials intended to be filed for FDA approval in cancer. With under $10 million in revenue

in 2009 and "several compounds in various stages of development," Incyte planned to commercialize the drug itself within the U.S. but to find a global pharmaceutical company to do so in the rest of the world. *Id.* Incyte negotiated the Agreement with Novartis to enable the parties to "develop and ultimately commercialize these compounds" with the "benefit from Novartis's significant and global expertise and know-how." *Id.* The parties planned to "collaborate and share expertise, intellectual property, and decision-making," thereby marketing ruxolitinib both domestically and abroad for mutual profit and patients' well-being world-wide. *Id.*[3]

B. The Collaboration And License Agreement

The Agreement creates a cross-licensing and cross-royalty arrangement for multiple drug compounds, including ruxolitinib.

Under that arrangement, each party holds the right to commercialize ruxolitinib within its Territory: Incyte's Territory was limited to the U.S., while Novartis's Territory comprised the rest of the world. Agreement §§ 1.48, 1.82. Under Article 2, the parties cross-licensed patent and other rights to enable Incyte to commercialize ruxolitinib in the U.S. and Novartis to do so abroad. As the holder of the only relevant intellectual property at the time of the Agreement, Incyte licensed Novartis to sell ruxolitinib only outside the U.S.: "an exclusive (even as to Incyte and its Affiliates), royalty bearing, non-transferable … license, … to (i) research, Develop, Commercialize, make, have made, use, offer ***for sale, sell and import*** JAK Licensed Compounds and JAK Licensed Products ***in the Novartis JAK Territory*** in the JAK Field and (ii) research, Develop, make and have made JAK Licensed Compounds and JAK Licensed Products in the

[3] The Agreement provided for licenses relating to a separate set of pharmaceutical products, the "c-MET Licensed Compounds." Agreement § 2.1(a). Those compounds and related products are not the subject of this dispute.

Incyte Territory ***for the sole purpose of using, offering for sale and selling*** JAK Licensed Products ***in … the Novartis JAK Territory***…." *Id.* § 2.1(b) (emphasis added).

Novartis also agreed to license to Incyte any intellectual property rights that Novartis might have or obtain in the future to sell ruxolitinib in the U.S. Although Novartis had no such patent rights when the Agreement was signed,[4] the Agreement contemplated that Novartis might develop and obtain patents (including U.S. patents) or improvements during the term of the Agreement—and that any such patented improvements would be licensed to Incyte for use in the U.S. *Id.* § 2.1(b). The Complaint is devoid, however, of any reference to a single patent Novartis held or has held that would cover sales of JAKAFI® in the U.S., and U.S. P.T.O. records show that Novartis never obtained any such patents. Thus, Novartis has licensed no patent rights to Incyte for U.S. sales.

Under the Agreement, each party pays royalties based on its annual sales of each Licensed Product in its respective Territory for a "Royalty Term." *See* Agreement § 8.3(a), (b). That term is defined as follows:

> Royalties … shall be paid … on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of each Licensed Product with respect to which royalty payments are due for a period which is the longer of: **(i)** the last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country; **(ii)** ten (10) years following the date of First Commercial Sale in such country; and **(iii)** the expiration of Regulatory Exclusivity for such Licensed Product in such country (each such term with respect to a Licensed Product and a country, a "Royalty Term").

Id. § 8.3(c). If, during the 10-year minimum Royalty Term, either (A) there is no further Valid Claim of Licensed Patent Rights that Covers a product in a country and Regulatory Exclusivity

[4] Thus, while Appendix A to the Agreement lists numerous foreign and domestic patents under "Incyte Patent Rights," there is no such list of Novartis patents appended.

has expired or (B) "Generic Competition" exists (the latter of which is not in dispute here), however, the royalty rate is reduced by 50% for the remainder of that Royalty Term:

> [I]n the event that either (A) the Royalty Term continues solely due to clause (ii) (i.e. in a specific country the Licensed Product is neither Covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity) or (B) Generic Competition exists with respect to a Licensed Product in a country with respect to a royalty-reporting period, then the royalty rates in such country for such Licensed Product (for such royalty-reporting period, if applicable) will be reduced to fifty percent (50%) of the applicable rate … beginning on January 1st of the Calendar Year following the first Calendar Year in which there exists a situation described in (A) or (B) of this sentence in the applicable country.

Accordingly, both the Royalty Term and the royalty rate currently in effect for Incyte's payments to Novartis depend on whether there is "any Valid Claim of Licensed Patent Rights" under clause (i) or "Regulatory Exclusivity" under clause (iii) for JAKAFI® in the U.S., or whether, as Incyte contends, the Royalty Term continues solely under the 10-year minimum term in clause (ii), in which case the royalty rate is reduced by 50% for the remainder of the 10-year term.

Sections 8.3(c)(i) and (iii) incorporate relevant defined terms. For Section 8.3(c)(i), the "Licensed Patent Rights" that must "Cover" the relevant Licensed Product are defined to mean, "***with respect to the Patent Rights licensed to Novartis hereunder***, the Incyte Patent Rights and ***with respect to the Patent Rights licensed to Incyte hereunder***, the Novartis Patent Rights." Agreement § 1.67 (emphasis added). Section 1.67 also used the phrase "[i]n each case," further emphasizing the separateness of the two prongs of the definition. *Id.* Notably, the terms "Patent Rights," "Incyte Patent Rights," and "Novartis Patent Rights" were separately defined, Agreement §§ 1.47, 1.79, 1.86, and were used in various provisions of the Agreement. In contrast, the definition of "Licensed Patent Rights" was used only in Section 8.3(c) and served a single purpose—to memorialize the parties' agreement as to the tenor and quantum of their respective royalty obligations.

As to Section 8.3(c)(iii), the parties defined "Regulatory Exclusivity" as "the ability to ***exclude*** Third Parties from Commercializing a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights." *Id.* § 1.101 (emphasis added). "Commercializing," is defined as "any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product." *Id.* § 1.19.

Finally, the Agreement includes an integration clause in Section 14.5:

> Entire Agreement; Amendments. This Agreement, the Supply Agreement and the Exhibits referred to in this Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Prior Confidentiality Agreement. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.

Although the parties have executed five amendments to the Agreement, *see* Mach Decl. Exs. 2-6, none concerns or relates to the subject matter of this dispute.

C. The Parties' Commercialization Of Ruxolitinib Under The Agreement

Incyte obtained FDA approval to sell JAKAFI® for the treatment of MF in November 2011. Compl. ¶ 23. At the time of approval, the FDA granted the drug two forms of regulatory exclusivity: New Chemical Entity ("NCE") exclusivity which gave exclusivity to ruxolitinib in ***all*** indications for five years and an "Orphan Drug Designation," which provided seven years of exclusivity (which runs consecutively with the NCE exclusivity) for only the MF indication *Id.* At that time, MF was the only approved indication, but Incyte later obtained FDA approvals and Orphan Drug Designations for two other indications: PV, in December 2014; and GVHD, in May 2019. *Id.* ¶ 24. Since its first commercial sale in November 2011, *id.* ¶ 31, Incyte has successfully

marketed JAKAFI® in the U.S., while Novartis has marketed ruxolitinib in European and other world-wide markets.

Although legally irrelevant to its claims and the merits of this motion, Novartis devotes substantial space in the Complaint to Incyte's alleged sales revenues for JAKAFI®. Novartis notes, for example, that Incyte grew its U.S. sales (as reported to the SEC) from about $2 million in 2011 to nearly $1.4 billion in 2018. Compl. ¶¶ 31-36. While Incyte takes these assertions as true for purposes of this motion, these sales figures have no relevance to the applicable Royalty Term or royalty rate here (which depends on the lack of Licensed Patent Rights and the expiration of Regulatory Exclusivity, not sales volumes). Novartis does not—cannot—allege that they do. But it bears noting that Novartis has profited enormously from sales in foreign markets. Novartis's 2018 Annual Report, for example, notes "strong demand" and lists annual sales of $977 million. *See* 2018 Novartis Annual Report, at 81, *available at* https://www.novartis.com/sites/www.novartis.com/files/novartis-annual-report-2018-en.pdf. To the extent Novartis suggests Incyte's sales volumes reflect any kind of inequity in the parties' benefits from the Agreement, the numbers tell a different story: Novartis, benefiting from a deal whereby it gained expansive licenses without having endured the huge risk and costs of initial drug research, earns strong revenues in its Territory as a result of the licenses granted by Incyte.

D. Expiration Of Orphan Drug Exclusivity For MF

The ODE for the MF indication expired in November 2018. Compl. ¶¶ 3, 23. Incyte subsequently reduced its calculation of the royalty on U.S. sales starting with its first-quarter payment for 2019, *i.e.*, reducing the rate beginning January 1, 2019 in a royalty report issued for that quarter on May 16, 2019. Compl. ¶ 38.

Novartis alleges that "Incyte did not send any contemporaneous notification to Novartis that said that the Step Down was coming into effect" as of November 2018, and "Incyte waited

over half of a year after the myelofibrosis ODE expired to take the position it is now taking." Compl. ¶ 38; *see also id.* ¶ 43. What Novartis does not state is that Incyte followed the process for invoking the step-down that is provided for in the Agreement. Under Section 8.3(c), the step-down does not commence on the first day that neither the Licensed Patent Rights condition nor the Regulatory Exclusivity condition is satisfied. Rather, the reduction to 50% of the otherwise applicable rate starts "beginning on January 1st of the Calendar Year following the first Calendar Year in which there exists" grounds for the step-down. Agreement § 8.3(c). Further, for any given quarter, the time for one party to notify the other of its royalty calculation is [redacted] after the end of [that] Calendar Quarter …." *Id.* § 8.4. Thus, Incyte's mid-May notice of its royalty calculation—incorporating the 50% step-down—was timely. Novartis thus does not—and cannot—contend that any of its allegations about Incyte's notification timing is legally relevant or supportive of its claims of breach. *See* Compl. ¶¶ 48-61.

Incyte's position has been consistent since the step-down came into effect. *See* Compl. ¶¶ 40, 42. First, Novartis never obtained U.S. patents, and so Incyte's U.S. sales of JAKAFI® have never been "Covered by a Valid Claim" of "Licensed Patent Rights" under Section 8.3(c)(i). Second, expiration of the ODE for the MF indication means that Incyte no longer has Regulatory Exclusivity—defined as a regulatory ability to exclude third party generic competitorss—under Section 8.3(c)(iii), because, following that expiration, Incyte can no longer rely on the regulatory status of JAKAFI® to exclude generic competitors from the market. Thus, the Royalty Term continues solely under Section 8.3(c)(ii) and the royalty rate is subject to reduction under Section 8.3(a).

E. The Complaint

The parties took their respective positions through the dispute resolution processes provided for in the Agreement, Compl. ¶¶ 45-47, without reaching resolution. Novartis then filed

its Complaint. Dkt. 1. The Complaint asserts claims for breach of contract and declaratory judgment, both on the basis that Incyte allegedly "improperly invoke[ed] the Step Down provision" with respect to royalties on U.S. sales of JAKAFI®. Compl. ¶ 50.

STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Pension Ben. Guar. Corp. ex rel. St. Vincent Catholic Med. Centers Ret. Plan v. Morgan Stanley Inv. Mgmt. Inc.*, 712 F.3d 705, 717 (2d Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

"In a dispute over the meaning of a contract, the threshold question is whether the contract is ambiguous." *Lockheed Martin Corp. v. Retail Holdings, N.V.*, 639 F.3d 63, 69 (2d Cir. 2011) (quoting *Krumme v. WestPoint Stevens Inc.*, 238 F.3d 133, 138 (2d Cir. 2000)). Incyte agrees with Novartis that the dispute concerns "application of unambiguous royalty terms," Compl. ¶ 1.[5] While the parties disagree on how those terms should be interpreted, "the mere fact that the parties disagree on the proper interpretation of the contract does not render the contractual language ambiguous." *Walker v. Thompson*, 404 F. Supp. 3d 819, 823 (S.D.N.Y. 2019). Where a plaintiff's claim "that he is entitled" to relief for breach of contract is, as here, "utterly refuted by the unambiguous terms of the contract," the proper course is dismissal at the pleading stage. *Wilson v. Poughkeepsie City Sch. Dist.*, 147 A.D.3d 1112, 1114 (2d Dep't 2017).

[5] The Agreement "represents the entire understanding of the parties to the transaction" because it includes an integration clause (Section 14.5), *Inv'rs Ins. Co. of Am. v. Dorinco Reinsurance Co.*, 917 F.2d 100, 104 (2d Cir. 1990)), and because it is facially complete, *Battery Steamship Corp. v. Refineria Panama, S.A.*, 513 F.2d 735, 738 n. 3 (2d Cir.1975) ("a contract which appears complete on its face is an integrated agreement as a matter of law").

ARGUMENT

Under New York law, which applies, *see* Agreement § 14.1 ("Governing Law"), "the elements of a breach of contract claim are (1) the existence of a contract, (2) performance by the party seeking recovery, (3) breach by the other party, and (4) damages suffered as a result of the breach." *See Johnson v. Nextel Commc'ns, Inc.*, 660 F.3d 131, 142 (2d Cir. 2011); *see Markov v. Katt*, 176 A.D.3d 401, 401-02 (1st Dep't 2019). Here, Incyte followed the unambiguous terms of the Agreement by invoking the 50% "step-down" of Section 8.3(c) in 2019 and has timely paid the reduced royalties due under the Agreement.

I. There Are No Licensed Patent Rights Covering Incyte's U.S. Sales Of JAKAFI®

Novartis asserts that JAKAFI® is "Covered by a Valid Claim of Licensed Patent Rights" within the meaning of Section 8.3(c)(i). Compl. ¶ 26. In support of this claim, Novartis references "eight patents," *id.*, but public records show, and Novartis does not allege otherwise, that each of those patents is a U.S. patent owned ***by Incyte***.[6] Because Incyte patents are irrelevant under the plain language of the Agreement for purposes of royalties paid by Incyte, JAKAFI® is not "Covered by a Valid Claim of Licensed Patent Rights" in the U.S., and never has been.

Analysis of this issue begins with the fact that, under Sections 8.3(b) and 8.3(c) of the Agreement, JAKAFI® is the "Licensed Product with respect to which royalty payments are due." Agreement § 8.3(c). Section 8.3(c)(i) provides that the tenor and quantum of Incyte's royalty obligation with respect to U.S. sales of JAKAFI® are affected by patents ***only*** to the extent that

[6] Novartis identifies the eight patents as: 7,598,257, 8,415,362, 8,722,693, 8,822,481, 8,829,013, 9,079,912, 9,814,722, and 10,016,429. Compl. ¶ 26. The U.S. P.T.O.'s website's records show that each is owned by Incyte. *Public Patent Application Information Retrieval*, U.S. PAT. AND TRADEMARK OFF., https://portal.uspto.gov/pair/PublicPair (last visited April 20, 2020). These are properly considered on a motion to dismiss. *Telebrands Corp. v. Del Labs., Inc.*, 719 F. Supp. 2d 283, 287 (S.D.N.Y. 2010) ("The Court may properly take judicial notice of official records of the United States Patent and Trademark Office and the United States Copyright Office.").

JAKAFI® is subject to (*i.e.*, "Covered by a Valid Claim of") "Licensed Patent Rights." The plain language of the Agreement makes clear that it is not.

The Agreement references patent rights in a variety of ways depending on context, and the fact that it does so deliberately should be honored in interpreting the contract. *See Givati v. Air Techniques, Inc.*, 104 A.D.3d 644, 645 (2d Dep't 2013) ("[A] court should not read a contract so as to render any term, phrase, or provision meaningless or superfluous.") (citing *God's Battalion of Prayer Pentecostal Church, Inc. v. Miele Assoc., LLP*, 6 N.Y.3d 371, 37 (2006)). Section 1.86 provides the broadest definition; it defines "Patent Rights" as encompassing "all patents and patent applications." Sections 1.47 and 1.79 are narrower definitions; they define, respectively, "Incyte Patent Rights" and "Novartis Patent Rights"—each of which is a subset of the broader term "Patent Rights" consisting of those rights "Controlled by" the named party. And Section 1.67 is even more narrowly focused; it incorporates each of those other definitions and uses them to define "Licensed Patent Rights" by reference to two separate "cases"—"***with respect to the Patent Rights licensed to Novartis hereunder***, the Incyte Patent Rights and ***with respect to the Patent Rights licensed to Incyte hereunder***, the Novartis Patent Rights." The parties deliberately chose to use a standalone definition of "Licensed Patent Rights" and to include in that definition the phrase "with respect to the Patent Rights licensed"—a term of limitation that would be superfluous and meaningless under Novartis's interpretation, but under New York law must be given effect. *See Cty. of Suffolk v. Alcorn*, 266 F.3d 131, 139 (2d Cir. 2001) ("It is axiomatic that courts construing contracts must give 'specific terms and exact terms … greater weight than general language.'") (citation omitted).

It would, of course, "violate[] a fundamental principle of contract interpretation" to "fail[] to give effect to a defined term." *Mionis v. Bank Julius Baer & Co.*, 301 A.D.2d 104, 109 (1st Dep't 2002). But Novartis asks this Court to do just that. Novartis's assertion that the tenor and

quantum of Incyte's royalty obligations are controlled by the continued existence of ***Incyte's*** U.S. patents would render superfluous both the definition of "Licensed Patent Rights" (because the definition was only used in Section 8.3(c)) and important words in the definition itself (because Novartis reads "Licensed Patent Rights" to mean "… the Incyte Patent Rights and … the Novartis Patent Rights"). And it would effectively rewrite Section 8.3(c)(i) to give the section the effect it would have had if the parties had used a different defined term, "Patent Rights"—or, alternatively, had combined two other defined terms to construct the phrase "Incyte Patent Rights or Novartis Patent Rights"—in that section.

But that is not what the parties did. Instead, the parties used a specific defined term—the single-purpose term defined in Section 1.67 and used only in Section 8.3(c)—to delineate a specific, limited set of "Patent Rights" that are to be considered in applying Section 8.3(c). Particularly when read in light of the other, broader definitions used elsewhere in the Agreement, that phrase—"Licensed Patent Rights"—serves the clear purpose of defining those patent licenses each party granted the other. The use of the phrases "with respect to" and "[i]n each case" in defining "Licensed Patent Rights" creates a clear directionality—the Patent Rights relevant to Incyte's royalty payments for U.S. sales are any Novartis Patent Rights which Novartis licensed to Incyte, while the Patent Rights relevant to Novartis's royalty payments for foreign sales are any Incyte Patent Rights which Incyte licensed to Novartis.[7] There is, quite simply, no other purpose

[7] Giving effect to the two-part structure of the definition of "Licensed Patent Rights" in Section 1.67 is consistent with the Agreement's definition of "Covering" and "Covered." Those terms are defined as meaning "that, ***but for a license granted to a Person*** under a Valid Claim included in the Patent Rights under which such license is granted, the Development, manufacture, Commercialization and/or other use of such product or the practice of such technology, process or method, by such Person ***would infringe such Valid Claim*** …." Agreement § 1.23 (emphasis added). Incyte does not need any license, from Novartis or anyone else, to manufacture, market, and sell JAKAFI® in the U.S. without infringing the eight patents Novartis relies on, because the claims and rights encompassed by those eight patents belong to Incyte in the first place. *See F.T.C.*

for the inclusion of those words in the definition—which Novartis invites this Court to rewrite by excising important words so that it would read, "Licensed Patent Rights means … the Incyte Patent Rights and … the Novartis Patent Rights." That is an invitation the Court should forcefully decline.

Because there are no Novartis Patent Rights applicable to Incyte's U.S. sales of JAKAFI®, there are no Licensed Patent Rights that could extend the tenor, or maintain the full quantum of, Incyte's royalty obligation to Novartis.[8]

While the interpretation of "Licensed Patent Rights" is a matter of plain language, it is also noteworthy that there is no hardship or unfair result associated with applying the Agreement's unambiguous terms. The step-down provision is mutual. As written, it provides that Incyte can extend the term of Novartis's royalty obligation and maintain its entitlement to the full contractual royalty rate by obtaining—and licensing to Novartis—additional Incyte Patent Rights that benefit Novartis in the Novartis Territory. And Novartis was afforded the exact same opportunity. Novartis could extend the term of Incyte's royalty obligation and maintain its entitlement to the full contractual royalty rate by obtaining—and licensing to Incyte—Novartis Patent Rights that would have benefited Incyte in the Incyte Territory. Novartis simply failed to do so. Thus, the

v. Actavis, Inc., 570 U.S. 136, 147, (2013) ("A valid patent excludes all ***except its owner*** from the use of the protected process or product …." (emphasis added)).

[8] Novartis's suggestion that a different result is required by the fact that Incyte granted Novartis a limited license under Section 2.1(b) to practice Incyte's U.S. patents in the U.S. for the purpose of facilitating Novartis's ability to sell ruxolitinib in Novartis's foreign territories ignores the two separate "cases" that the parties built into the definition of "Licensed Patent Rights." Nor is there any merit to Novartis's argument, in its pre-motion letter, that "Incyte's interpretation … reads out language (including § 2.l(b)(ii))." Dkt. 19 at 3. Section 2.1(b)(ii) serves a particular purpose—allowing Novartis to conduct activities, short of selling ruxolitinib, in the U.S. And it serves that purpose notwithstanding the fact that Section 8.3(c) was drafted in such a way as to distinguish between "Patent Rights" generally and the case-specific phrase "Licensed Patent Rights" and so to ensure that neither party's Royalty Terms or amounts would be affected by its own patents.

bargain that the parties struck—and that is memorialized in the plain language of the Agreement—makes perfectly good commercial sense.

II. Regulatory Exclusivity Ended For JAKAFI® When MF Orphan Drug Exclusivity Expired, As Incyte No Longer Has A Regulatory Ability To Exclude Third Party Competition

When Incyte began selling JAKAFI® in the U.S. in 2011, the drug was FDA-approved for a single indication—MF—and the FDA had granted Incyte an Orphan Drug Designation under the Orphan Drug Act for that indication. That designation afforded Incyte a seven-year period of ODE for what was, at the time, the drug's only indication. It is undisputed that ODE expired for the MF indication on November 16, 2018. Compl. ¶ 29. It also is undisputed that the FDA has granted Incyte two additional Orphan Drug Designations, with attendant seven-year ODE periods, for two additional indications—PV and GVHD. *Id.* ¶ 24. Novartis cites these latter designations as "regulatory exclusivities" that "cover two of the three indications" for JAKAFI® (*id.* ¶¶ 19, 28), and asserts that, because they remain in force today, JAKAFI® remains subject to "Regulatory Exclusivity" within the meaning of Section 8.3(c)(iii). Under Novartis's reading of the Agreement, therefore, "Regulatory Exclusivity" for JAKAFI® will expire only after ODE status has expired for every indication for which the drug is approved. Novartis's argument cannot be reconciled with the plain language of the Agreement.

For this reason, Novartis's Complaint seeks to obscure that plain language with repeated references to "regulatory exclusivit***ies***." Compl. ¶ 28. What is at issue here, however, is the term "Regulatory Exclusivity," which is defined in Section 1.101 as:

> "the ***ability to exclude*** Third Parties from ***Commercializing*** a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights."

"Licensed Product" is defined by Section 1.61 as "a product or product candidate that contains one or more JAK Licensed Compounds as the active ingredient …" In other words, it means a ruxolitinib product, regardless whether that product is labeled for treatment of one, two, or all three medical indications for which JAKAFI® is approved. And "Commercializing" is defined in Section 1.19 to mean:

> "any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing offering to sell, and/or selling a product (including establishing the price for such product."

Because generic competitors would be engaging in Commercialization if they were to conduct ***any*** of these activities with respect to a generic version of JAKAFI®, Incyte has the "ability to exclude" such competitors from Commercializing a generic version—such that "Regulatory Exclusivity" has not expired—only if the regulatory status of JAKAFI® affords Incyte the ability to "exclude" those generic competitors from the market entirely. The fact that JAKAFI® retains ODE for PV and GVHD plainly does not exclude such "Commercialization" of ruxolitinib from the entire market, because there is *no regulatory barrier* to third parties from bringing to market a generic version of JAKAFI® for the indication of MF. There is no regulatory barrier to third parties bringing to market a generic for the MF indication.

Pharmaceuticals are, of course, heavily regulated in the U.S. and elsewhere. In the U.S., an Orphan Drug Designation is part of one such regulatory regime. Sponsors, like Incyte, that receive Orphan Drug Designations qualify for certain benefits, one of which is a seven-year ODE period. *See* 21 U.S.C. § 360cc(a). During that seven-year period, the holder of the ODE has the exclusive right to market the drug specifically for the particular orphan drug ***indication***. *See* 21 C.F.R. § 316.31(a) ("FDA will not approve another sponsor's marketing application for the same drug ***for the same use or indication*** before the expiration of 7 years from the date of … approval" of an orphan drug designation) (emphasis added).

ODE has been described as "[o]ne of the more often cited but least understood aspects of the Orphan Drug Act." IQVIA Institute for Human Data Science, Orphan Drugs in the United States 5 (Dec. 2018) (https://www.iqvia.com/-/media/IQVIA/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations-pdf). It is clear, however, that ODE "is indication-based rather than drug-based." *Id.* at 9. This means that "the protection provided by orphan designation does not prevent generic competition on any non-orphan indications after patent expiry, nor on orphan indications when the exclusivity has expired." *Id.* "[T]he exclusivity does not directly inhibit generics from competing in the other approved uses of a multi-indication drug." *Id.* at 8.

Thus, Incyte's "Regulatory Exclusivity" ended once the ODE status for the MF indication expired. When that happened, Incyte was not, and is still not able, to rely on the Orphan Drug Designations for two other indications to exclude generic manufacturers from Commercializing ruxolitinib. Based on the current FDA regulatory status of JAKAFI®, generic competitors are able to "market," "promote," distribute," "import," "offer to sell," and "sell" ruxolitinib. All of these activities fall squarely within the definition of Commercialization. While it is true that generic competitors cannot promote ruxolitinib for the PV and GVHD indications, this means, at most, that there are some activities that fall within the definition of Commercialization—far less than all—in which they cannot engage. To limit Third Parties' ability to conduct some subset of activities that would constitute Commercialization of ruxolitinib (*i.e.*, labeling and promoting it for two indications) is not the same as an ability to "exclude" such parties from Commercializing the Licensed Product, ruxolilinib. Under the plain text of the Agreement, therefore, ODE status for PV and GVHD do not constitute "Regulatory Exclusivity."

This result is dictated by the plain words of the Agreement. It goes without saying that the application of Section 8.3(c)(iii) is guided by the contractual definitions of the defined terms used in the section. It is equally clear, moreover, that the contractual definitions must be interpreted based on plain and ordinary meaning of any undefined terms within them. *See Carlton Grp., Ltd. v. Mirabella SG SpA*, 2018 WL 3520494, at *6 (S.D.N.Y. July 19, 2018) ("Absent an express definition for any of these terms, each is understood according to its plain meaning.") (citing *Eckman v. Eckman*, 999 N.Y.S.2d 494, 495 (2d Dep't 2014)). *See also 10 Ellicott Square Court Corp. v. Mountain Valley Indem. Co.*, 634 F.3d 112, 120 (2d Cir. 2011) ("[i]t is common practice for the courts of [New York] to refer to the dictionary"). Here, the key undefined terms hold that Regulatory Exclusivity is the "the ***ability to exclude*** Third Parties from Commercializing a Licensed Product"—*i.e.*, exclude them from "***any*** activities directed" toward bringing a product to market. In common parlance, "exclude" means "to prevent the entrance of" or "to bar from participation," and "any" means "one or some indiscriminately of whatever kind,"—frequently used as a synonym for "all" or "every." Merriam Webster Online Dictionary, available at https://www.merriam-webster.com/.[9] Regulatory Exclusivity thus requires, expansively, an

[9] Even if the Court should find that certain of these words may be ambiguous in the abstract, the Agreement is not ambiguous because "[i]n deciding whether an agreement is ambiguous, '[p]articular words should be considered, not as if isolated from the context, but in the light of the obligation as a whole and the intention of the parties as manifested thereby.'" *Collins v. Harrison-Bode*, 303 F.3d 429, 433 (2d Cir. 2002) (quoting *Kass v. Kass*, 91 N.Y.2d 554, 566, 696 N.E.2d 174, 180 (1998)). *See also Alden Glob. Value Recovery Master Fund, L.P. v. KeyBank Nat'l Ass'n*, 159 A.D.3d 618, 625-26 (1st Dep't 2018) ("The existence of ambiguity must be determined by examining the entire contract and considering the relation of the parties and the circumstances under which it was executed, with the wording to be considered in the light of the obligation as a whole and the intention of the parties as manifested thereby.") (internal quotations and alterations omitted). In the context of the parties' Agreement and the drafter's intent evidenced by the contract as a whole, the phrase, "ability to exclude" "any activities" to bring a product to market, unambiguously is not met if Incyte ***cannot*** exclude some activities because it has no regulatory right to prevent third parties to market and sell the drug labeled to treat the MF indication only.

ability to prevent third-party competition completely. And because, as noted above, a "Licensed Product" is defined based on what its active ingredient is, not what disease it is indicated to treat, once Incyte no longer has a regulatory ability to prevent a third party from introducing a competitor to JAKAFI® and to promote it for MF, Regulatory Exclusivity ends whether or not Incyte can still prevent third parties from labeling their generic alternative for the treatment of PV or GVHD.

As a matter of pharmaceutical law, that has been the applicable regulatory status since November 2018, following the expiry of ODE for MF. That is because a drug maker may, without violating exclusionary rights, market a generic drug for a subset of those indications for which the drug is approved and exclude indications for which regulatory exclusivities still exist. This practice, known as "skinny labeling" or "carve-out labeling" has been approved by FDA regulations. *See* 21 C.F.R. § 314.94(a)(8) ('Labeling—(iv) Labeling … proposed for the drug product must be the same as the labeling approved for the reference listed drug, except … differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include … omission of an indication or other aspect of labeling protected by patent or accorded exclusivity [by the FDA]"). It has also been recognized and approved by federal courts. *See, e.g.*, *Spectrum Pharm., Inc. v. Burwell*, 824 F.3d 1062, 1066 (D.C. Cir. 2016) ("Labeling carve-outs are so named because any exclusive use is carved out, *i.e.*, omitted, from the list of approved uses on the generic's label. FDA allows labeling carve-outs under the Orphan Drug Act …."); *Otsuka Pharm. Co. v. Burwell*, 2015 WL 1962240, at *10 (D. Md. Apr. 29, 2015) ("[T]he statute, case law, and FDA regulations all support the FDA's construction of the statute

that allows it to carve out an indication or other information from ANDA labeling when that indication or information is protected by orphan drug exclusivity….").[10]

The correct meaning of the Agreement—that "Regulatory Exclusivity" for a product may expire notwithstanding that certain regulatory limitations on third-party marketing activities for some indications remain in force—is also confirmed by the rules that apply to the Orphan Drug Act. Courts have held, in that context, that ODE does not protect a drug ***in all its indications***, but only with respect to an indication subject to that exclusivity. *See Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141, 145 (4th Cir. 2002) ("Congress made clear its intention that [section 360cc] was to be disease-specific, not drug-specific. In other words, the statute as written protects uses, not drugs for any and all uses."). The implication of this framework is that, after ODE expired for the MF indication, its remaining ODEs for the PV and GVHD indications provide no protection against generic competition labeled for use to treat MF. Thus, once the MF exclusivity expired, Incyte lost its regulatory "ability to exclude Third Parties from Commercializing" ruxolitinib in the U.S. to treat patients for the MF indication. In light of this, there is no question that the parties' unambiguous intent in defining "Regulatory Exclusivity" was that it would expire once a party could not protect a product from third party competition for at least one indication.[11]

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[10] Novartis itself engages in "skinny labeling" to market its own generic versions of drug compounds where one, but not all, indications lose their ODE or other right to exclude competition.

[11] But for Incyte's patent protections, the potential that the expiration of ODE for MF will lead to generic competition for MF alone is very real for Incyte's business, because MF treatment accounts for a large share of JAKAFI® sales. Many states require, by "automatic substitution laws, that once a generic option is available on the market, pharmacists fill the lower-price generic in lieu of the brand label version. *See, e.g.*, N.Y. Educ. Law § 6816-a ("A pharmacist shall substitute a less expensive drug product containing the same active ingredients" when certain requirements are met). The expiry of ODE for MF thus has serious potential consequences for Incyte, reinforcing why the parties agreed to language ending "Regulatory Exclusivity" once a regulatory-based exclusivity expired for at least one indication.

Here, again, as with the issue of Licensed Patent Rights, Incyte's reading of the term Regulatory Exclusivity comports with commercial reasonableness and imposes no hardship or unfair result on Novartis. Indeed, Novartis's alternative reading of the term is itself commercially unreasonable. Accepting Novartis's reading would mean that every time Incyte successfully obtains approval for the use of JAKAFI® to treat a new rare disease/indication, it would be financially penalized by an extension of the higher royalty. That would also work to penalize patients of rare disease in need of such drug approvals. Given that Novartis is a sophisticated party, if the parties had intended this counter-intuitive result—for the higher royalty term to continue as long as any single indication retained a regulatory exclusivity—the parties would have made that intent express in Section 8.3(c)(iii). Instead of defining a special term, "Regulatory Exclusivity," the parties would have used language similar to that used in Section 8.3(i)'s condition ("the last to expire of any Valid Claim of Licensed Patent Rights"). In other words, Section 8.3(c)(iii) would read "the last to expire of any regulatory exclusivities" instead of "expiration of Regulatory Exclusivity." The parties did not write the contract that way, and the Court should not accept Novartis's invitation to re-write the Agreement to obtain that absurd result.

Novartis's position also contradicts legally recognized realities of the pharmaceutical market. As courts have recognized, expiration of ODE for one indication often means that a competing generic drug will also be prescribed for indications that still retain regulatory exclusivities, because "[n]o matter what use for the drug is described on the label … FDA does not prevent a doctor from prescribing a drug for some other use, called an "off-label" use. *See Bristol–Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1496 (D.C. Cir. 1996). Expiration of ODE, should it lead to third-party competitor products labeled for MF, will also like impair Incyte's ability to successfully market for PV and GVHD. The parties naturally contracted for a royalty

program by which Incyte does not continue to pay royalties at a rate and for a term premised on the ability to exclude third party competition, when the commercial reality is that such ability to exclude no longer existed.

CONCLUSION

The Court should grant Incyte's motion to dismiss the Complaint in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2020, I electronically filed the foregoing with the Clerk of the Court using CM/ECF. I also certify that the foregoing is being served this day on all counsel of record via transmission of Notice of Electronic Filing generated by CM/ECF.

/s/ Richard I. Werder, Jr.
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